510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K083878.

1) Applicant Name and Address

JUN 2 5 2010

Applicant:	r2 Diagnostics, Inc.
Address:	1801 Commerce Drive South Bend, IN 46628
Contact Person:	Marc D. Goldford
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Date of Preparation:	23 Jun 2010

2) Device Name(s)

Trade Name:	LupoTek Detectin VL LupoTek Correctin VL
Classification Name:	Reagent, Russell Viper Venom (21CFR 864.8950, Product Code GIR)

Trade Name:	PlasmaCon LA
Classification Name:	Abnormal control plasma (21CFR 864.5425, Product Code GGC)

3) Predicate Device(s)

LupoTek Detectin VL: Diagnostica Stago DRVV Screen (K061805)
LupoTek Correctin VL: Diagnostica Stago DRVV Confirm (K061805)
PlasmaCon LA: American Diagnostica LAtrol Abnormal Control (K935254)

4) Device Description(s)

LupoTek Detectin VL and LupoTek Correctin VL use *Vipera lebetina* venom rather than *Vipera russelli* (Russell's Viper) venom in the dRVVT assay for lupus anticoagulant. *Vipera lebetina* venom, like Russell's viper venom, will directly activate Factor X without requiring Factor VII. The activated Factor X in conjunction with Factors V, II, calcium ions and phospholipid will generate thrombin which converts fibrinogen to fibrin, producing a clot in the test system. LupoTek Detectin VL, the low phospholipid reagent, is designed as the screening reagent to detect a prolongation of the clotting time. LupoTek Correctin VL is the high phospholipid reagent that neutralizes the LA and corrects the clotting time to normal, confirming the presence of a Lupus Anticoagulant.

PlasmaCon LA is a lyophilized Lupus Anticoagulant (LA) positive plasma suitable for use as a quality control plasma for *in vitro* diagnostic assays in the clinical coagulation laboratory sensitive for the presence of LA

5) Intended Use(s)

LupoTek Detectin VL and Correctin VL test kits are qualitative tests intended to aid in the detection of lupus anticoagulants (LA) in citrated human plasma by the dilute Russell's viper venom method in professional clinical laboratories.

PlasmaCon LA is intended for use as an LA positive, abnormal quality control plasma to monitor the performance of diagnostic assays, performed in professional clinical laboratories, for the presence of lupus anticoagulants in citrated plasma.

6) Technological Characteristic Summary

The *in vitro* diagnostics device(s) presented in this 510(k) submission, LupoTek Detectin VL, LupoTek Correctin VL, and PlasmaCon LA are substantially equivalent, respectively, to the Stago DRVV Screen, Stago DRVV Confirm, and American Diagnostica LAtrol Abnormal Control *in vitro* diagnostics devices.

One hundred fifty-five patient samples with various clinical conditions including LA were analyzed in three sites with the LupoTek Detectin VL / Correctin VL and the Stago DRVV Screen / Confirm kits. The percent positive agreement was 98% and the percent negative agreement was 96%.

Comparisons of the submitted kits and their respective predicate kits are summarized in the tables below:

Table 1: Comparison of submitted devices LupoTek Detectin VL and Correctin VL to predicate device Stago DRVV Screen and Confirm		
Similarities		
Item	Submitted Device	Predicate Device
Intended use	LupoTek DetecTin VL and CorrecTin VL test kits are qualitative tests intended to aid in the detection of lupus anticoagulants (LA) in citrated human plasma by the dilute Russell's viper venom method in professional clinical laboratories.	The STA Staclot dRVV Screen and STA Staclot dRVV Confirm kits are intended for the detection of the lupus anticoagulants(LA) in plasma by the dilute Russell's viper venom test (1) performed with analyzers of the STA line suitable to these reagents.
Patient sample	Citrated human plasma	Citrated human plasma
Measurement principle	*Vipera lebetina* venom, like Russell's viper venom, will directly activate Factor X without requiring Factor VII. The activated Factor X in conjunction with Factors V, II, calcium ions and phospholipid will generate thrombin which converts fibrinogen to fibrin, producing a clot in the test system. The LupoTek DetecTin VL is designed as the screening reagent to detect a prolongation of the clotting time. The LupoTek CorrecTin VL is a high phospholipid reagent that neutralizes the LA and corrects the clotting time to normal, confirming the presence of a Lupus Anticoagulant.	Lupus anticoagulants are antibodies directed against phospholipid/protein complexes. Staclot® dRVV Screen test is performed with a low phospholipids concentration reagent to screen samples. If lupus anticoagulants are present, the clotting time will be prolonged. The Staclot® dRVV Confirm Reagent contains a higher phospholipids concentration to neutralize the LA present in the plasma to be tested. The clotting time obtained with the Staclot® dRVV Confirm Reagent will be shorter than the one observed with the Staclot® dRVV Screen reagent.
Format	Lyophilized reagents consisting of venom, phospholipid, anti-heparin agent, calcium, buffers, stabilizers, and a dye.	Lyophilized reagents consisting of venom, phospholipid, anti-heparin agent, calcium, buffers, and stabilizers.
Analyte	Lupus anticoagulants	Lupus anticoagulants
Differences		
Item	Submitted Device	Predicate Device
Venom source	Vipera lebetina	Vipera russelli
Color	Detectin VL: Blue Correctin VL: Pink	Screen: Green Confirm: Light Orange
Reconstituted Stability	2-8C: 24 hr RT: 8 hr	2-8C: not listed RT: not listed On-board STA Compact: 72 hrs.

Table 2: Comparison of submitted device PlasmaCon LA to predicate device American Diagnostica LAtrol Abnormal Control		
Similarities		
Item	Submitted Device	Predicate Device
Intended use	PlasmaCon LA is intended for use as an LA positive, abnormal quality control plasma to monitor the performance of diagnostic assays, performed in professional clinical laboratories, for the presence of Lupus Anticoagulants (LA) in citrated human plasma.	The LAtrol Abnormal control and LAtrol Normal control plasmas have been developed for use as part of daily quality control procedures for Lupus Anticoagulant (LA) testing.
Constituent material	Citrated human plasma positive for Lupus Anticoagulant(s).	Citrated human plasma positive for Lupus Anticoagulant(s).
Measurement principle	The Lupus Anticoagulant(s) in the abnormal control plasma lengthen the clotting times of LA sensitive diagnostic assays.	The Lupus Anticoagulant(s) in the abnormal control plasma lengthen the clotting times of LA sensitive diagnostic assays.
Format	Lyophilized plasma	Lyophilized plasma
Analyte being tested	Lupus anticoagulants	Lupus anticoagulants
Differences		
Item	Submitted Device	Predicate Device
Reconstituted Stability	2-8C: 8 hr RT: 4 hr	2-8C: 8 hr (RT: not listed)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

R^2 Diagnostics
c/o Mr. Marc D. Goldford
Director, Research and Development
1801 Commerce Drive
South Bend, IN 46628

JUN 25 2010

Re: k083878
Trade/Device Name: LupoTek DetecTin VL
LupoTek CorrecTin VL
PlasmaCon LA
Regulation Number: 21 CFR §864.8950
Regulation Name: Russell viper venom reagent
Regulatory Class: Class II
Product Code: GIR, GGC
Dated: April 21, 2010
Received: April 22, 2010

Dear Mr. Goldford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K083878

Device Name: PlasmaCon LA

Indication For Use: PlasmaCon LA is intended for use as an LA positive, abnormal quality control plasma to monitor the performance of diagnostic assays, performed in professional clinical laboratories, for the presence of lupus anticoagulants in citrated plasma.

Prescription Use __X____ And/Or Over the Counter Use_____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083878

Indication for Use

510(k) Number (if known): K083878

Device Names: LupoTek Detectin VL and LupoTek Correctin VL

Indication For Use: LupoTek DetecTin VL and CorrecTin VL test kits are qualitative tests intended to aid in the detection of lupus anticoagulants (LA) in citrated human plasma by the dilute Russell's viper venom method in professional clinical laboratories.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use_____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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